

# Safety Evaluation Of The Clear Hand HYGIENIC HAND GEL Finished Cosmetic Product

subject to the requirements of Article 10 of cosmetic Regulation (EC) No 1223/2009

## 1. Evaluation conclusions

The Clear Hand HYGIENIC HAND GEL finished product as defined in Article 3 of Regulation (EC) No 1223/2009. is **safe for human health** when used under the conditions of its intended use and / or use under reasonably foreseeable conditions of use.

The classification of a product as safe for human health is the sum and comparison of the information obtained from:

- the physical and chemical properties of the components,
- toxicological data on the components,
- ecological data on the components,
- use under intended and / or reasonably foreseeable conditions,

This evaluation applies only to Clear Hand HYGIENIC HAND GEL cosmetic finished products that have the exact same composition as the CPNP Application ID.

## 2. Warnings and instructions on the label

The labeling of the Clear Hand HYGIENIC HAND GEL cosmetic product shall contain the mandatory labeling information required by Article 19 (1) (a) to (g) of Regulation (EC) No 1223/2009 and shall meet the labeling requirements of Article 19 (1), (2), (5), and (6) of that Regulation. .

- a. Contact details of the responsible person are stated on the label, and Product Information Documentation is available.
- b. The nominal content at the time of packing is indicated by the packing volume.
- c. The finished cosmetic product has a shelf life of more than 30 months, indicating the date from when it will be opened and used safely and without adverse consequences for the consumer.  
This information is contained in Annex VII to the Regulation. It shall be indicated by the symbol given in point 2 of Annex II, followed by a period of 12 M.

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- d. The labeling does not list special precautions for the use of the finished cosmetic product because the composition of the product, Articles IV to VI of the Regulation. For substances listed in Annexes I and II, the use of the product under normal and / or reasonably foreseeable conditions shall not be justified.
- e. The batch number or identification number of the finished cosmetic product is placed on the 250 ml bottle.
- f. The purpose of the finished cosmetic product, on the one hand, and its appearance and, on the other hand, the instructions for use giving satisfactory information, are reassuring.
- g. The ingredients of the finished cosmetic product are listed using the common name in the Glossary / INCI name. The ingredients are listed in descending order of weight at the time they are added to the cosmetic product after the term "Ingredients".

### 3. Justification

The justification is based on the data collected in Part A of the Safety Report on a Clean Hand HYGIENIC HAND GEL Cosmetic Product.

#### **Safety assessment of substances and / or mixtures in the finished cosmetic product:**

a. Hazard characterization of substances and mixtures

The Clear Hand HYGIENIC HAND GEL finished cosmetic product

- consists of ingredients which, at the given concentration and for the intended use, do not present any hazards to health, based on their general toxicological profile.
- do not contain any contaminants / traces the amount of which would endanger the health of the user. The materials used in the preparation of Clear Hand HYGIENIC HAND GEL cosmetics have been certified by the safety data sheets to be of cosmetic quality and to comply with the relevant requirements for impurities and traces, so that they are not present in the finished product in quantities endangering the health of the user.
- do not contain any substances included in Annex II to Regulation (EC) No 1223/2009 which are not authorized/are prohibited for use in cosmetic products.
- do not contain any substances listed in Annex VI to Regulation (EC) No 1223/2009; Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), category 1A or 1B listed in Part 3 of Annex II.
- do not contain nano-sized materials.
- do not contain substances of concern and / or substances of pH values related to CPNP Rules 1-18

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- the form used - the o / v hydrophilic gel - stable, homogeneous and the components do not react chemically with one another. The finished cosmetic product is a two-phase system, the base is water. The presence of physico-chemical systems in the finished cosmetic product exhibits appropriate visco-elastic behavior while retaining the properties of non-Newtonian fluids.
- compatibility test with primary packaging has not been performed. The primary packaging material, Polyethylene (PE) Bottle, is widely used for the packaging of cosmetic products. According to the manufacturer's written declaration, the packaging materials are compliant with requirements.

Contained in the Decree 1223/2009/EK (2009.Nov.30.)

Contained in Decree 1907/2006/EK (2006.Dec.18.)

Contained in Decree 10/2011/EK (2011.Jan.14.)

The packaging material is a polyethylene bottle system that fulfills its dual function in terms of its protective role:

- protects the product from external environmental influences whilst ensuring quality,
- protects the external environment from the effects of the product.
- complies with the prohibition on animal testing in Article 18 of Regulation (EC) No 1223/2009

The representative of Primavera-Cosmetic Kft stated that in the development of the Clear Hand HYGIENIC HAND GEL cosmetic product, no animal experiments were carried out or entrusted to anyone. Manufacturers of raw materials do not use animal testing to comply with Regulation (EC) No 1223/2009 and have carried out toxicological studies using an alternative method adopted by the EU, in accordance with OECD guidelines.

b. Assessment of local and systemic exposure (based on absorption data)

Megállapítható, hogy a Clear Hand HYGIENIC HAND GEL kozmetikai késztermék az abszorpció valamennyi jelentős toxikológiai lehetőségét és szisztémás hatásait figyelembe vevő Biztonsági Határ (MoS) számítási eredményei alapján, az emberi egészségre vonatkozóan biztonságosnak tekinthető. A kozmetikai termék valamennyi összetevője esetén a MoS  $\geq 100$ .

It can be concluded that the Clear Hand HYGIENIC HAND GEL cosmetic product is considered safe for human health based on the calculation of the Safety Limit (MoS), which takes into account all significant toxicological potentials and systemic effects of absorption. The cosmetic product MoS  $\geq 100$  for all components.

The Dermal Absorption of Substances in Clear Hand HYGIENIC HAND GEL cosmetic product depends on

**firstly**, its own characteristics (eg log Pow, molecular weight), its concentration in the composition,

**secondly**, on its behavior in its surroundings

The ingredients of the cosmetic product have their own characteristics in the safety data sheets of the manufacturer. The behavior in the surroundings is shown in the properties of the classic o / v emulsion.

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The systemic exposure (SED) value of the components is represented by the calculated daily value  $SED = \text{Product Component} \times \% \text{Component in Product} \times \text{DAP\%} / 100$ .

It is a positive expectation that the cosmetic product ingredients have SED values as low as possible, especially with low NOAEL values, in other words, the NOAEL / SED values should be as high as possible, which is the expectation of the Clear Hand HYGIENIC HAND GEL cosmetic finished product.

c. Risk assessment of systemic effects (calculation of safety margin) and of local effects (eg skin allergy, skin irritation).

Clear Hand HYGIENIC HAND GEL has MoS  $\geq 100$  for all ingredients in the finished cosmetic product. MoS = NOAEL / SED. For substances with a MoS  $\geq 100$ , the substance is safe for human health if it has been established by the NOAEL in animal experiments.

Clear Hand HYGIENIC HAND GEL Cosmetic is a finished product within the meaning of:

- Annex III to Regulation (EK) No 1223/2009 Annex II does not contain any restricted allergenic fragrance or flavoring components registered under numbers 67 to 92.
- it does not contain any of the preservatives listed in Annex V to Regulation (EK) No 1223/2009.
- photosensitising effect is not presumed.
- does not contain irritating ingredients

During the additional safety assessment of the Clear Hand HYGIENIC HAND GEL finished cosmetic product

- the compatibility of the skin type with the finished cosmetic product did not reveal any actual and / or presumed safety risk.
- synergistic / antagonistic effects of the ingredients have not been investigated.
- the possible chemical reactions between the components have not been investigated, and no chemical reaction is expected or anticipated in view of the properties of the formulation used, based on normal heat and pressure conditions of the human lifestyle.

**Based on the above, the composition of the Clear Hand HYGIENIC HAND GEL cosmetic product complies with the requirements of Regulation (EK) No 1223/2009.**

**Safety assessment of the finished cosmetic product**

The Clear Hand HYGIENIC HAND GEL cosmetic product('s):

- as defined in Regulation (EK) No 1223/2009, is not a cosmetic product intended for use on children under 3 years of age and is not subject to the specific recommendations in the notes of the FBTB Guide.
- ingredients have been carefully evaluated by the CIR (Cosmetic Ingredient Review) and found safe at this use and concentration.

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- safety assessment has taken into account the results of physical, chemical and microbiological testing of both the substances and the finished cosmetic product, on the basis of which the product is stable and has good local tolerance.
- (for safety reasons) production is carried out in accordance with good manufacturing practice (GMP) which harmonises with the requirements of EN ISO 22716, fulfilling the requirement of Article 8 (1) of Regulation (EK) No 1223/2009.
- is checked and sampled in a reliable and reproducible manner in accordance with Article 12 of Regulation (EK) No 1223/2009. The production batches are produced with the appropriate quality certificate.
- microbiological purity of production batches is checked according to EU standard, manufacturing of cosmetic product according to GMP principles minimizes the risk of microbiological contamination during production.
- shelf life test is unrequired, the high alcohol content provides the data expected from the product.
- real-time shelf-life studies have been carried out which are adequate to evaluate the shelf life of the finished cosmetic product. Taking into account the knowledge gained during the marketing of similar products and formulations, the obtained data support the results of real-time shelf life studies. Shelf life of the finished cosmetic product is  $\geq 30$  months and 12 months from the date of opening (PAO).
- presentation, shape, odor, color, external appearance, packaging, labeling and size are not such as to endanger any confusion with food, in accordance with Article 3 (a) of Regulation (EC) No 1223/2009 and Council Directive 87/357 / EEC health and safety of consumers.
- function is declared in the consumer information text and consumers are adequately informed about the composition of the preparation. The consumer information text shall comply with the requirements of the cosmetic product and shall be based on the precautionary principle. It does not contain misleading claims regarding the efficacy of the finished cosmetic product.
- contains ingredients that help to achieve the desired purpose and to achieve the desired cosmetic effect(s).
- contains skin softening and conditioning substances that make the skin soft and smooth, keeping it in good physiological condition. Its moisturizing and skin protection components keep and retain moisture, helping to prevent the skin from being exposed to external influences.
- in accordance with Article 21 of Regulation (EC) No 1223/2009, a frame formulation and additional information to assist consumers in making an informed choice in the product information file is available to consumers.
- after being placed on the market - for identification within the supply chain and for safe marketing - is able to identify the distributors to whom they are supplying the finished cosmetic product. The required documentation is available during the distribution of the finished product.

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The Clear Hand HYGIENIC HAND GEL finished cosmetic product has been evaluated according to the Cosmetics Regulation (EK) No 1223/2009.

#### 4. Qualification of inspector and Part B approval

Pursuant to Article 10 (2) of Regulation (EC) No 1223/2009, the Security Officer shall be „a holder of a diploma or a formal qualification recognized as an academic or practical study in pharmacy, toxicology, medicine or related sciences or recognized as equivalent by the Member States .”

**The Clear Hand HYGIENIC HAND GEL finished cosmetic product has been screened for safety by:**

dr.univ.Mandl Károly grad. pharmacist, specialized pharmacist  
H-1155 Budapest Széchenyi út 3.

Qualifications:

1977 Certified Pharmacist,  
SZOTE University of Szeged, Faculty of Pharmacy

Scientific degree:

1981 Post.grad Doctor of Pharmacy, Ph.D. (dr.univ) SOTE Semmelweis University of Medicine  
1993 Specialist Pharmacist, National Institute of Pharmacy, OGYI (National Institute of Pharmacy)

Professional experience:

Pharmacist,	Chinoín Rt
Technological research lab leader,	Chinoín Rt
Pharmacy Manager,	Mátyás Király Pharmacy
College teacher, microbiology	Wesley János Lelkészképző College

Professional representation:

Membership of the Hungarian Chamber of Pharmacists

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Taking into account the outcome of the safety assessment in Part B of this Safety Report,

**a Clear Hand HYGIENIC HAND GEL finished cosmetic product**

when used under conditions for which it is intended or reasonably foreseeable,

**is safe for human health.**



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dr.univ.Mandl Károly  
security inspector  
okl. pharmacist, specialized pharmacist

This conclusion applies only to the finished cosmetic product, Clear Hand HYGIENIC HAND GEL, whose composition is in all respect consistent with the data provided in the safety assessment file and the laboratory examination. The safety data sheet for the finished cosmetic product should in any case be updated, in the light of any further relevant information obtained after the finished product has been placed on the market. It is the responsibility of the person responsible to ensure that this is the case, including compliance with Article 10 (1) (c) of Regulation (EC) No 1223/2009 Cosmetics Regulation.

Made: Budapest, March 3<sup>rd</sup>, 2020

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